IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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|---|---|---|
| Forest Laboratories Inc., Forest Laboratories Holdings Ltd., Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH, | ) | |
| Plaintiffs, | ) | |
| v. | ) | C. A. No. 08-021-GMS-LPS |
| Cobalt Laboratories Inc., Lupin Pharmaceuticals Inc., Lupin Ltd., Orchid Pharmaceuticals Inc., Orchid Chemicals & Pharmaceuticals Ltd., Teva Pharmaceuticals USA Inc., Upsher-Smith Laboratories Inc., Wockhardt USA Inc. and Wockhardt Limited, | ) | |
| Defendants. | ) | |

**ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Upsher-Smith Laboratories, Inc. ("USL"), as its Answer to the Complaint filed by Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Plaintiffs"), states as follows:

**PARTIES**

1. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1.

2. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2.

3. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 3.

4. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4.

5. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5.

6. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6.

7. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7.

8. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8.

9. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9.

10. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10.

11. USL admits that it is a Minnesota corporation having a principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota 55369. USL admits that it manufactures generic drugs for sale and use throughout the United States, including in this judicial district. USL is without knowledge or information sufficient to form a belief as to the truth of the allegation that the generic drugs it manufactures are "numerous," as that term is vague and undefined.

12. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12.

13. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13.

**NATURE OF THE ACTION**

14. USL admits that the Complaint purports to state a cause of action under the United States patent laws, 35 U.S.C. § 100 *et seq*. USL admits that the Complaint purports to allege infringement of United States Patent No. 5,061,703 ("the '703 patent"). USL denies any remaining allegations contained in paragraph 14.

**JURISDICTION AND VENUE**

15. Denied.

16. USL admits that this Court has personal jurisdiction over USL in this action. USL denies any remaining allegations contained in paragraph 16.

17. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17.

18. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 18.

19. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 19.

20. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20.

21. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21.

22. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22.

23. USL admits that this Court has personal jurisdiction over it in this action, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 23.

24. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 24.

25. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 25.

26. USL admits that venue is proper in this judicial district, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 26.

**THE PATENT-IN-SUIT**

27. USL admits that the '703 patent is entitled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia." USL admits that the '703 patent is dated October 29, 1991. USL denies that the '703 patent was "duly and legally issued" by the United States Patent and Trademark Office ("PTO"). USL is without knowledge or information sufficient to form a belief as to the truth of the allegation that "Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance." To the extent that "Merz" in the allegations refers to Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH collectively, as set forth in paragraph 4 of the Complaint, USL denies the allegation that "Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance."

28. USL is without knowledge or information sufficient to form a belief as to the truth of the allegation that "Forest" is the exclusive licensee of the '703 patent in the United States. To the extent that "Forest" refers to Forest Laboratories, Inc. and Forest Laboratories Holdings,

Ltd., collectively, as set forth in paragraph 2 of the Complaint, USL denies the allegations that "Forest is the exclusive licensee of the '703 patent in the United States" and "Forest holds NDA No. 21-487." USL is without knowledge or information sufficient to form a belief as to the truth of the allegation that Forest holds New Drug Application ("NDA") No. 21-487 for Namenda® brand memantine hydrochloride tablets. USL admits that the '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalent Evaluations* ("Orange Book") for Namenda®, and denies any remaining allegations contained in paragraph 28.

29. USL is without knowledge or information sufficient to form a belief as to the truth of the allegation that "Forest" is the exclusive distributor of Namenda® in the United States. To the extent that "Forest" refers to Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., collectively, as set forth in paragraph 2 of the Complaint, USL denies the allegation that "Forest" is the exclusive distributor of Namenda® in the United States.

30. USL admits that on August 18, 2004, Merz Pharma GmbH & Co. KGaA submitted a request to the PTO for reexamination of the '703 patent. To the extent that "Merz" refers to Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH collectively, as set forth in paragraph 4 of the Complaint, USL denies the allegation that "Merz" submitted a request to the PTO for reexamination of the '703 patent. USL admits that the PTO issued a reexamination certificate for the '703 patent on November 7, 2006.

## ACTS GIVING RISE TO THIS ACTION

### Count I – Infringement Of The '703 Patent By Defendant Cobalt

31. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 31.

32. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 32.

33. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 33.

34. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 34.

35. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 35.

36. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 36.

**Count II – Infringement Of The '703 Patent by Defendants Lupin And Lupin Pharma**

37. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 37.

38. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 38.

39. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 39.

40. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 40.

41. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 41.

42. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 42.

43. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 43.

44. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 44.

**Count III – Infringement Of The '703 Patent By Defendants Orchid And Orchid Pharma**

45. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 45.

46. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 46.

47. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 47.

48. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 48.

49. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 49.

50. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 50.

51. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 51.

52. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 52.

**Count IV – Infringement Of The '703 Patent By Defendant Teva**

53. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 53.

54. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 54.

55. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 55.

56. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 56.

57. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 57.

58. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 58.

**Count V – Infringement Of The '703 Patent by Defendant Upsher-Smith**

59. Admitted

60. USL admits that it alleged in its ANDA No. 90-043 pursuant to 21 U.S.C. § 335(j)(2)(A)(vii)(IV) that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the proposed commercial manufacture, use, or sale of generic tablet products containing 5 milligrams, 10 milligrams, 15 milligrams, and 20 milligrams of memantine hydrochloride ("the Upsher-Smith Generic Products"). USL denies that it has engaged in, or is currently engaging in, any commercial manufacture, use or sale of Upsher-Smith Generic Products. USL is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 60.

61. Denied.

62. Admitted.

63. Denied.

64. Denied.

**Count VI – Infringement Of The '703 Patent By Defendants Wockhardt And Wockhardt USA**

65. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 65.

66. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 66.

67. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 67.

68. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 68.

69. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 69.

70. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 70.

71. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 71.

72. USL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 72.

## ANSWER TO PRAYER FOR RELIEF

USL denies that Plaintiffs are entitled to the judgment and relief contained in paragraphs A through F of the Plaintiffs' prayer for relief.

## AFFIRMATIVE DEFENSES

### Lack of subject matter jurisdiction

The Court lacks subject matter jurisdiction over this action.

### Failure to state a claim

The Complaint fails to state a claim upon which relief can be granted.

### Noninfringement

USL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '703 patent.

### Patent Invalidity

The '703 patent and all the claims therein are invalid under 35 U.S.C. § 101 *et seq.* including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and 305.

### Defenses to Equitable Relief

Plaintiffs are not entitled to equitable relief because they cannot establish the prerequisites to obtaining equitable relief, including having clean hands.

### Estoppel

Plaintiffs are estopped from asserting infringement under the doctrine of equivalents and are barred from asserting certain claim interpretations because of amendments and arguments made to the United States Patent and Trademark Office to secure allowance of the claims of the '703 patent.

**No Recovery of Costs**

Plaintiffs are barred from recovering any costs in this action pursuant to 35 U.S.C. § 288.

**Patent Misuse**

The '703 patent is unenforceable due to patent misuse.

**Inequitable Conduct**

The '703 patent is unenforceable due to inequitable conduct by the patent owner Merz Pharma GmbH & Co. KGaA ("Merz Pharma") during patent prosecution, including reexamination, because Merz Pharma, with intent to deceive the examiner, breached its duty of candor by deliberately failing to disclose material information and submitting materially false information to the PTO. A reasonable examiner would have been substantially likely to consider the information withheld and the misinformation submitted important in deciding the patentability of the '703 patent.

The PTO issued the original '703 patent on October 29, 1991. The '703 patent, on its face, claims priority to 1989. The original patent included thirteen claims, all of which were directed to a method for the treatment of cerebral ischemia using an adamantane derivative, although one dependant claim recited the treatment of Alzheimer's disease as well.

In 2004, Merz Pharma requested the PTO to reexamine the '703 patent. During the reexamination, Merz added new claims and amended the then-existing claims. The PTO issued the new, reexamined claims in 2006. Each reexamined claim contains the newly added limitation "diagnosed with Alzheimer's disease," thereby limiting the scope of the '703 Patent to the prevention and treatment of cerebral ischemia in patients diagnosed with Alzheimer's disease. Claim 10 of the reexamined '703 patent has an additional claim limitation requiring that the use of the claimed method must also be "for the treatment of Alzheimer's disease."

During reexamination, the patent examiner initially rejected most of the claims of the '703 patent as unpatentable under 35 U.S.C. § 102(b) in light of four prior art references that were not before the examiner during the original prosecution. The examiner determined that these references taught that memantine "is effective in treating cerebral ischemia and Alzheimer's disease or complications associated with the two disorders." To overcome the rejection, Merz Pharma introduced a declaration by Myron Weiner, M.D. dated May 5, 2005 to explain why efficacy of memantine to treat Alzheimer's disease was "unexpected" in 1989.

To reach the conclusion that memantine had an "unexpected" efficacy against Alzheimer's disease, the Weiner Declaration asserted that "[i]n 1989, there was no evidence to suggest that memantine had any activity at the NMDA receptor." Further, it stated that "the use of NMDA receptor antagonism in general would have been contraindicated for the treatment of Alzheimer's disease in 1989 because it was thought that blocking of NMDA receptor function would result in reduced cognition and greater vulnerability to excitotoxicity."

In contrast to these allegedly mistaken beliefs prevalent in 1989 about memantine and NMDA receptor antagonists, Dr. Weiner explained the action of memantine as follows:

> 16. ... Specifically, memantine is an uncompetive, low to moderate affinity NMDA receptor antagonist that helps to ameliorate the consequences of imbalanced neuronal stimulation. This imbalance is characterized by a major increase in excitatory amino acids, which allows an excessive influx of calcium through NMDA receptor channels. This excessive calcium influx leads to a progressive loss of brain cells, as seen in Alzheimer's disease. By its unique manner of blocking the NMDA receptor, memantine prevents the excessive influx of calcium that leads to degeneration and loss of brain cells. In summary, by reducing neuronal impairment or damage, memantine effectively treats patients diagnosed with Alzheimer's disease. (Emphasis added.)

By filing this declaration, Merz Pharma sought to overcome the examiner's rejection by convincing him that memantine, through its action of blocking the NMDA receptor, stops or

reduces the degeneration of neurons in Alzheimer's patients.

This Declaration was materially false and misleading and failed to apprise the examiner of the material fact that there was, in fact, no evidence that memantine had the declared effect in Alzheimer's patients. Indeed, Dr. Weiner's declaration is directly contradicted by the FDA-approved drug label for Namenda® (memantine hydrochloride). In 2003, while applying for the FDA approval to use memantine hydrochloride to treat Alzheimer's disease, Forest Pharmaceuticals, Inc., a subsidiary of Forest Laboratories, Inc. (Merz's Licensee), conceded in explicit terms that "[t]here is no evidence that memantine prevents or slows neurodegeneration in patients with Alzheimer's Disease." The same statement is used on Namenda®'s drug label until this day. Accordingly, even *now*, nearly twenty years after the original application of the '703 patent was filed, there is no evidence that the claimed methods prevent or slow neuronal degeneration in patients with Alzheimer's disease. The information evidencing a lack of efficacy of memantine in Alzheimer's patients to prevent neurodegeneration was highly material to the patentability of the '703 patent claims, yet it was not disclosed to the PTO during the reexamination of the '703 patent between 2004 and 2006, or at any other time during the prosecution of the '703 patent.

Merz Pharma was aware of the state of knowledge concerning the action of memantine and was intimately involved in the development and testing of the drug. Merz Pharma entered into a license and cooperation agreement with Forest Laboratories, Inc. in 2000 for the explicit purpose of developing memantine for the treatment of Alzheimer's disease. As soon as Namenda® was approved by the FDA for such treatment, Merz Pharma announced the news on February 20, 2004, noting that Axura®, which is the trade name for memantine in Europe, had been approved for the same indication in Europe since 2002. Merz Pharmaceuticals GmbH,

which allegedly shares the same principal place of business as Merz Pharma at Frankfurt am Main, Germany, is authorized to market Axura® for the treatment of Alzheimer's disease in Europe.

In conclusion, Merz Pharma was aware of material information adverse to its interests during the reexamination, but failed to disclose it to the PTO prior to the issuance of the '703 patent in 2006. Instead, Merz Pharma introduced and relied on the deceptive and misleading Weiner Declaration to show the efficacy of the claimed method in patients diagnosed with Alzheimer's disease and to overcome the rejection by the PTO based on anticipation by prior art references. The totality of circumstances shows that Merz Pharama had an intent to deceive the patent examiner during the reexamination of the '703 patent.

The inequitable conduct detailed above by Merz Pharma during the prosecution of the '703 patent (including its reexamination) renders the '703 patent unenforceable.

WHEREFORE, USL prays this Court:

A. Enter an Order dismissing the Complaint, with prejudice, for lack of subject matter jurisdiction.

B. Enter an Order dismissing the Complaint, with prejudice, for failure to state a claim upon which relief can be granted.

C. Enter a judgment that USL has not infringed the '703 patent.

D. Enter a judgment that all claims of the '703 patent are invalid.

E. Enter a judgment that the '703 patent is unenforceable due to patent misuse.

F. Enter a judgment that the '703 patent is unenforceable due to inequitable conduct.

G. Enter an order dismissing the Complaint, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever.

H. Find this case to be exceptional and award USL its reasonable attorneys' fees and costs incurred in this litigation.

I. Award USL such other and further relief as the nature of the case may require and as the Court may deem just, proper and equitable.

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Dated: February 1, 2008

**CERTIFICATE OF SERVICE**

I hereby certify that on February 1, 2008, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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